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HOVEY WILLIAMS LLP
10801 Mastin Blvd., Suite 1000
Overland Park, KS 66210

EXAMINER	
PORTER, RACHEL L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/802,546	WHITSON, DEBI	
	Examiner	Art Unit	
	Rachel L. Porter	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,9-11,13,14 and 17-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-7,9-11,13-14,17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the RCE filed 10/31/2007. Claims 1-2, 4-7,9-11,13-14,17-21 are pending.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

Response to Amendment

3. The declarations under 37 CFR 1.132 filed 10/31/07 are insufficient to overcome the rejection of claim 1 (18 or 20) based upon Kimak (USPAP 2005/0187794 A1) and Kraftson et al (USPN 6,151,581) under 35 U.S.C. 103(a) because the declarations fail to set forth facts

(A) Retah Kwan Declaration

It states that the claimed subject matter solved a problem that was long standing in the art. However, there is no showing that others of ordinary skill in the art were

working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04.

(B) Debi Whitson Declaration

Within the declaration, the Applicant suggests that the invention has met with commercial success. The commercial success must be derived from the *claimed* invention and must flow from the functions and advantages disclosed or inherent in the specification. While the declaration provides information on sales, gross sale sales figures do not show commercial success absent evidence as to market share. Applicant must also show that any success is not the result of heavy advertising or promotion.

MPEP 716.03 provides further guidance:

> In considering evidence of commercial success, care should be taken to determine that the commercial success alleged is directly derived from the invention claimed, in a marketplace where the consumer is free to choose on the basis of objective principles, and that such success is not the result of heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the claimed invention, etc. *In re Mageli, 470 F.2d 1380, 176 USPQ 305 (CCPA 1973)* (conclusory statements or opinions that increased sales were due to the merits of the invention are entitled to little weight); *In re Noznick, 478 F.2d 1260, 178 USPQ 43 (CCPA 1973).*
>
> In ex parte proceedings before the Patent and Trademark Office, an applicant must show that the claimed features were responsible for the commercial success of an article if the evidence of nonobviousness is to be accorded substantial weight. See *In re Huang,* 100 F.3d 135, 140, 40 USPQ2d 1685, 1690 (Fed. Cir. 1996) (Inventor's opinion as to the

purchaser's reason for buying the product is insufficient to demonstrate a nexus between the sales and the claimed invention.). Merely showing that there was commercial success of an article which embodied the invention is not sufficient. Ex parte Remark, 15 USPQ2d 1498, 1502-02 (Bd. Pat. App. & Inter. 1990).

4. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1,4-6,9,11,13-14, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable Kimak (USPAP 2005/0187794 A1) over Kraftson et al (USPN.6,151,581- hereinafter Kraftson).

[claim 1] Kimak discloses a process of forming an electronic medical record, the method comprising of the steps of:

c) arranging the data stream of patient data into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient specific medical record; (par. 47-48, par. 64-65, par. 70-71; Figure 3) See Also par. 66-67

d) sending the formatted data to an assigned location for importing into the patient's patient-specific medical record, wherein the electronic medical record contains specific information regarding the patient's health (par. 66-67, par. 70)

Kimak further discloses obtaining patient information from disparate sources (par. 68,71) but does not expressly disclose that the data is obtained by providing the patient with a machine-readable questionnaire concerning the patient's health.

Kraftson discloses :

a) providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67)

b) interfacing a machine readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream; (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

Claim 1 further recites providing the patient with a machine-readable card including a questionnaire.

Kraftson discloses a process further comprising providing the patient with a machine-readable card including a questionnaire (i.e. is a paper answer sheet comprised of questions with designated areas for patient responses.) (Figures 2A-C, col. 7, lines 3-11). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to include machine-readable card including a questionnaire.

One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

[claim 4] Kimak and Kraftson teach the method of claim 1 as explained in the rejection of claim 1. Furthermore, Kraftson teaches a process wherein the machine-readable questionnaire includes questions concerning the systems making up the human body with designated locations for patient responses and is accomplished by a member of the clinical staff. (Col. 11, lines 43-58; Figures 2A-C; 3A-C; Figure 13—Receptionist/staff helps provide patient questionnaire.) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson for the reasons set forth in the rejection of claim 1.

[claim 5] Kimak and Kraftson teach the method of claim 1 as explained in the rejection of claim 1. Kraftson teaches a process wherein the step of interfacing the machine- readable card with the scanning type machine is accomplished by a member of the clinical staff. (col. 6, lines 1-10; col. 7, lines 3-10; col. 20, lines 5-8, lines 43-69 (e.g. Clinical staff member receives E-PDS and downloads the information patient information by connecting to the host device) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to

modify the method of Kimak with the teaching of Kraftson for the reasons set forth in the rejection of claim 1.

[claims 6] Kimak discloses a process, further comprising the step of arranging the data stream into a defined format structure simulation the protocol of Health Level 7 (HL7) (par. 66)

[claim 9] Kimak teaches a process further comprising a step of receiving the formatted data with an interface engine (par. 57-58) and sending it to the database containing the patient's electronic medical record. (par. 65-67)

[claim 11] Kimak and Kraftson teach the process of claim 4 as explained in the rejection of claim 4. Furthermore, Kraftson discloses a process wherein the machine-readable card is a paper answer sheet comprised of questions with designated areas for patient responses. (Figures 2A-C, col. 7, lines 3-11). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to include a paper survey for the motivation provided in the rejection of claims 1 and 4.

[claim 13] Kimak discloses the method of claim 9 wherein said database is any database that accepts HL7 or ASTM messaging. (par. 34, par. 66)

[claim 14] Kimak and Kraftson disclose the method of claim 1 as explained in the rejection of claim 1. Kimak further discloses a process comprising the step of arranging the data stream into a defined format structure simulation the protocol of Health Level 7 (HL7) (par. 66) disclose receiving the data stream from the scanning type device. However, at the time of the Applicant's device, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak and Kraftson to accept the data stream from the scanning device. One would have been motivated to include this feature to facilitate the transfer electronic medical records from heterogeneous sources into a central registry. (Kimak: par. 3)

[claim 18] Kimak discloses a method for supplementing a medical record with medical information comprising the steps of:

- communicating the formatted data to an electronic medical record interface and adding the information to the patient's personal medical record, wherein the patient's personal medical record contains patient specific, clinical information regarding the patient's health; and (par. 47, 63-66)
- presenting the information to a physician as part of the patient's personal electronic medical record. (par. 87)

Kimak discloses obtaining patient information from disparate sources (par. 68,71) but does not expressly disclose that the data is obtained by providing the patient with a machine-readable questionnaire concerning the patient's health.

Kraftson discloses a method of obtaining patient information with information submitted by a patient, the method comprising the steps of:

- receiving from the patient a machine-readable printed form containing information about a health status of the patient; (Figures 2A-2C, 3A-3C,13; col. 5, line 65-col. 6, line 3; col. 11, lines 43-58; col. 14, lines 28-67)
- electronically scanning the printed form to convert the information to machine processable data and communicate the data to a computer; (Figures 1 and 4; col. 7, lines 3-10)
- formatting the machine-processable data with the computer so that the data is in a form that may be communicated to an electronic medical record; (col. 7, lines 6-10;col. 9, lines 32-49; col. 13, lines 59-61)

At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain patient information. One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

[claim 19, 21] Kimak discloses presenting the patient's electronic medical record to the physician, before the patient visits the doctor to apprise the physician of the patient's health status in the patient's absence. (par. 47,76, and 86). However, Kimak does not expressly disclose that the data is obtained from a questionnaire or that the

questionnaire is mailed to a patient prior to an appointment. Kraftson discloses a method, further comprising the step of mailing the form to the patient prior to the appointment; and (col. 11, lines 9-13—Patients see doctors for the first time or on an ongoing basis to update information and may opt to fill out survey prior to any of their appts.) At the time of the Applicant's invention, it would have been to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to mail a form/questionnaire to the patient to be completed before and appointment. As suggested by Kimak, one would have been motivated to include this feature to allow the point of care providers to become more informed and to become part of a network is updated with medical (e.g. immunization) information. (par. 47) 1-2, 4-7,9-11,13-14,17-21

[claim 20] The limitations of claim 20 are substantially similarly to claims 14 and 18. As such, claim 20 is addressed by the rejections of claims 14 and 18, and incorporated herein.

7. Claims 2, 10, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimak and Kraftson as applied to claim 1 above, and further in view of Oyama et al (USPN 5,496,175).

[claims 2 and 10] Kimak and Kraftson teaches a system/method of gathering and entering patient data into a patient database using professional staff members, (col. 7,

lines 3-11) but does not expressly disclose inputting information using a microcomputer compatible keyboard. Oyama discloses a questionnaire system wherein data gathering and input of questionnaire/survey data occurs using PC's with keyboards (col. 6, lines 21-36) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kraftson with the teaching of Oyama to allow manual input of data using a keyboard. As suggested by Oyama, one would have been motivated to include these features to increase the diversity of information that may be input into the system from the questionnaire data. (col. 1, line 55-col. 2, line 2).

[claim 17] Kimak and Kraftson teach a process wherein the computer processor is a standard PC (col. 8, lines 60-63; col. 19, lines 21-25). Kimak and Kraftson do not expressly disclose the specifications of the computer. However, Applicant provides no explanation in the specification as to why the recited specifications (32 MB of hard drive space and a processor capable of operating at 100 MHz) provide an advantage over other processor speeds and memory requirements. Moreover, it is respectfully submitted that at the time of the applicant's invention, a hard drive with at least 32 MB of memory and a processor with at least a 100 MHz processor were well known in the computer arts. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to include a computer with at least 32 MB of hard drive memory and at least a 100 MHz processor speed in the system of Kraftson and Oyama in combination with the motivation of making

the method available to medical practices and individuals with limited computer resources.

8. Claim 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimak and Kraftson as applied to claim 1 above, and further in view of Applicant's Admission of prior art (page 8, lines 6-8 of 6/20/06 Applicant's response.)

[claim 7] Kimak and Kraftson disclose the method of claim 1 as explained in the rejection of claim 1. Kraftson discloses a survey system and method for obtaining patient information from a questionnaire (Figure 2A-2C; col. 5, line 65-col. 6, line 3) and converting the obtained information into a data stream (col. 6, line 5-10; col. 7, lines 3-10; Figure 4), but does not expressly disclose the specific formats that are accommodated by the system. However, it is noted that HL7, ANSI, and ASTM are well known in the art for establishing transmitting and formatting standards for data. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kimak and Kraftson in combination to accommodate HL7, ANSI or ASTM protocol standards. One would have been motivated to include this feature to facilitate the transmission, storage, and analysis of patient data, as suggested by Kraftson (col. 2, lines 56-63).

Response to Arguments

9. Applicant's arguments filed 10/31/07 have been fully considered but they are not persuasive.

(A) The Applicant argues the combination of Kimak and Kraftson, the Examiner has provided no reason why a person of ordinary skill in the art would combine the teachings of Kimak and Kraftson as proposed by the Examiner.

In response, *KSR* forecloses Applicant's argument that a *specific* teaching, suggestion or motivation is required for a finding of obviousness. See *Ex parte Smith* 83 USPQ2d 1509 *(citing KSR*, 127 S.Ct. at 1741, 82 USPQ2d at 1396)

Moreover, in the present case, the Examiner submits that the motivations have been provided for each of the combinations which support the holding of obviousness in the rejections of claims 1,4,6,18, and 20, In each case, the motivations for the combinations are found in one or more the references themselves or would have been in the knowledge generally available to one of ordinary skill in the art.

Claims 1,4,6,18, and 20 recite combinations which unite old elements with no change in their respective functions and which yield predictable results.

The first part of the process in this invention is to provide a patient with a questionnaire in the form of a "bubble" scan card (a paper based form with questions and designated areas for patient responses) when arriving at the medical facility. They are also given a pencil and asked to mark the "bubbles" for their answers. Next, the data from the machine readable scan card is scanned to convert the patient's written answers into an electronic data stream, as disclosed by Kraftson and explained in the rejection of independent claims 1, 18, and 20 claims.

Moreover, on page 2, lines 11-19 of the Background of the Invention, the Applicant explains that HL-7 formats have long used as a standard in the medical

industry, and "govern the format for data exchange between scheduling, billing, medical records and laboratory systems." The Kimak reference provides further evidence that HL7 has long been used as a standard for electronic interchange of data. (par. 0005) As cited in the rejections of claims 1,4,6,18, and 20,

(B) Applicant further argues that Kraftson is non-analogous to the applicant's invention.

In response to applicant's argument that Kraftson is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

In this case, both the applicant's invention and the Kraftson reference are drawn to medical surveys, and are therefore in the same field of endeavor. In particular, both inventions are deal with "providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67)" and "interfacing a machine readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream." Therefore, both the reference and the applicant's invention are attempting to address some of the same problems in the art, and the Kraftson reference is not seen as a non-analogous reference.

Furthermore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

(C) The Applicant argues that Kimak does not "import information into the patient's electronic record, as recited in claim 1, but rather uses electronic medical records already created by physicians."

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "import information into a patient's record...") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It should be noted that the last positively and actively recited step in claim 1 is the "(d) sending of formatted data to an assigned location..." The claim does not recite actively recite a step of "importing information into a patient's electronic medical record." Moreover, there is nothing in the current claim language that precludes any imported data from being added to a medical record created by physicians, which Applicant argues is a distinction of the instant invention over the prior art.

Similarly, claim 20 fails to positively recite the step of "importing information into a patient's electronic medical record." Again, the last step recited in claim 20 is a communication step: "communicating the formatted data to an electronic medical record interface engine..."

In both instances, the importation of data is recited as future or intended use, a step which does not necessarily occur within the scope of the instant claim. For example in claim 1, step d) recites "**sending the formatted data to an assigned location** *for* importation into the patient's patient specific record." Similarly claim 20, recites, "**communicating the formatted data to an electronic medical record interface engine** *to* automatically add the information to the patient's personal electronic medical record."

Claim 18 underscores the distinction in scope and Applicant's apparent intent in not positively and actively reciting the active importation of data into the patient record. In other words, claim 18 is in fact the only independent claim in which the Applicant actively recites the both the communication of data and the addition of data to the patient record. ("**communicating the formatted data** to an electronic medical record interface **and adding the information** to the patient's personal medical record....")

Moreover, Kimak discloses sending or communicating the formatted data to an assigned location (e.g. an electronic medical record interface engine) and importing or adding the information into the patient's patient-specific medical record,

wherein the electronic medical record contains specific information regarding the patient's health. On page 5, (par. 66-73) of Kimak, patient data from disparate sources is formatted into HL7 format then sent through a match/merge module and added to the registry database. (par. 66-70) Patient data includes patient immunization history/records (patient-specific data) and is retrievable by patient name or IPID (immunization patient identification) (par. 72, 74).

The rejection of claims 1 and 20 are proper, and should be upheld.

(D) Applicant further argues that Kimak does not receive data from users, only remote servers.

Again, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., receiving data directly from users) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Moreover, the term "users" is broad enough to encompass server owners/operators, and physicians, as well as patients.

As to Applicant's assertion that there is not suggestion or motivation to modify Kimak as proposed in the Office Action to receive data directly from a patient via a machine readable questionnaire, *KSR* forecloses Applicant's argument that a *specific* teaching, suggestion or motivation is required for a finding of obviousness. See *Ex parte*

Smith 83 USPQ2d 1509 *(citing KSR*, 127 S.Ct. at 1741, 82 USPQ2d at 1396)

Moreover, in the present case, the Examiner submits that the motivations have been provided for each of the combinations which support the holding of obviousness in the rejections of claims 1, as well as claims 4,6,18, and 20, In each case, the motivations for the combinations are found in one or more the references themselves or would have been in the knowledge generally available to one of ordinary skill in the art.

(E) Applicant argues that Kraftson and Kimak fail to disclose how information from the patient survey forms could be arranged "into a defined data structure simulating the protocol from a party having authorization to export data to the patient's" electronic medical record.

In response to Applicant's argument that the system of Kimak cannot be combined with the system of Kraftson, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Kimak was relied upon to disclose c) arranging the data stream of patient data into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient specific medical record. (par. 47-48, par. 64-65, par. 70-71; Figure 3; See also Par. 66-67) Kimak discloses how patient

data is obtained from disparate sources, appropriately formatted, and added the main registry.

Kimak does not expressly disclose that the data is obtained by providing the patient with a machine-readable questionnaire concerning the patient's health.

Consequently, Kraftson was relied upon to disclose a) providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67). Kraftson further teaches b) interfacing a machine readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream; (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

It was this combination of references, and a motivation cited from the Kraftson to support the holding of obviousness.

(F) Applicant argues that the Kraftson reference teaches anonymous surveys, and therefore does not disclose the Applicants limitations.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The Kraftson reference discloses the use of machine-readable questionnaires as a well-established method of obtaining data at the time of Applicant's invention. Kraftson also discloses providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67). Kraftson further teaches interfacing a machine-readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream (converting from printed to electronic form) (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

Kimak stores itself includes patient specific data. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain the patient information. One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

Furthermore, it is noted that Kraftson does not envision that the surveys be used only to gather patient satisfaction data or that there be complete patient anonymity with the surveys of the invention. (Kraftson col. 11, lines 24-58) The reference discusses patients filling out demographic and diagnostic/treatment sections of the questionnaire as requested by personnel.

(G) Applicant argues that the prior art does not teach the limitations of claim 4.

Again, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Kimak and Kraftson teach the method of claim 1 as explained in the rejection of claim 1. Furthermore, Kraftson teaches a process wherein the machine-readable questionnaire includes questions concerning the systems making up the human body with designated locations for patient responses and is accomplished by a member of the clinical staff. (Col. 11, lines 43-58; Figures 2A-C; 3A-C; Figure 13—Receptionist/staff helps provide patient questionnaire.) Kraftson further discloses in sections that the patient completes sections survey sections including diagnostic and treatment sections (i.e. questions *concerning* systems making up the human body).

(H) Applicant argues that the reference fails to disclose the limitations of claim 6, because of the "anonymity requirements" of Kraftson.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The data within the Kimak reference itself is patient specific and includes patient identifiers. (Figure 3; par. 74) As such, Kimak does disclose a process, further comprising the step of arranging the data stream into a defined format structure simulation the protocol of Health Level 7 (HL7) (par. 66)

The Kraftson reference discloses the use of machine-readable questionnaires as a well-established method of obtaining data at the time of Applicant's invention. Kraftson also discloses providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67). Kraftson further teaches interfacing a machine-readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream (converting from printed to electronic form) (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain the patient information. One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

Furthermore, regarding Applicant's assertion that the Kraftson surveys must be anonymous, it is submitted Kraftson does not envision that the surveys be used only to gather patient satisfaction data or that there be complete patient anonymity with the surveys of the invention. (Kraftson col. 11, lines 24-58). The reference discusses patients filling out demographic and diagnostic/treatment sections of the questionnaire as requested by personnel.

Applicant's discussion of Forrey and McDonald articles also underscores the universality of HL7 format in the medical field. Moreover, while Applicant argues that HL7 has only been used to communicate traditional laboratory, it is noted that the current language of claims fails 1 and 6 fails to distinguish Applicants use in the instant invention from the traditional well-known use of HL7 or the use described in the applied prior art. In other words, the type of data captured, converted and communicated in claim 6 is "patient's medical history, environment, symptoms, or other pertinent information." Traditional laboratory test data would address at least one the required categories of medical information.(e.g. medical history, environment (e.g., high/low electrolytes; dehydration; blood lead levels); other pertinent medical information).

(I) Applicant argues that the prior art does not disclose the limitations of claim 18, namely the use of forms to collect patient information and presenting the information to a physician as part of a patient's medical record.

Kimak discloses sending or communicating the formatted data to an assigned location (e.g. an electronic medical record interface engine) and importing or adding the information into the patient's patient-specific medical record, wherein the electronic medical record contains specific information regarding the patient's health. On page 5, par. 66-73 of Kimak, patient data from disparate sources is formatted into HL7 format then sent through a match/merge module and added to the registry database. (par. 66-70) Patient data includes patient immunization history/records (patient-specific data) and is retrievable by patient name or IPID (immunization patient identification) (par. 72, 74). Kimak further discloses presenting the information to a physician as part of the patient's personal electronic medical record. (par. 87)

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The Kraftson reference discloses the use of machine-readable questionnaires as a well-established method of obtaining data at the time of Applicant's invention. Kraftson also discloses providing the patient with a machine-

readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67). Kraftson further teaches interfacing a machine-readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream (converting from printed to electronic form) (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

Kimak stores itself includes patient specific data. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain the patient information. One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

Regarding Applicant's assertion that the Kraftson surveys must be anonymous, it is noted Kraftson does not envision that the surveys be used only to gather patient satisfaction data or that there be complete patient anonymity with the surveys of the invention. (Kraftson col. 11, lines 24-58). The reference discusses patients filling out demographic and diagnostic/treatment sections of the questionnaire as requested by personnel.

(J) Applicant argues that Kimak and Kraftson do not teach the limitations of claim 20.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Kimak discloses a process, further comprising the step of arranging the data stream into a defined format structure simulation the protocol of Health Level 7 (HL7) (par. 66) (The data within the Kimak reference itself is patient specific and includes patient identifiers. (Figure 3; par. 74))

The Kraftson reference discloses the use of machine-readable questionnaires as a well-established method of obtaining data at the time of Applicant's invention. Kraftson also discloses providing the patient with a machine-readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; 3A-3C; col. 5, line 65-col. 6, line 3, lines 41-52; col. 11, lines 43-58; col. 14, lines 28-67). Kraftson further teaches interfacing a machine-readable questionnaire card with a scanning type machine to convert the patient's written answers to a data stream (converting from printed to electronic form) (col. 5, lines 1-6; col. 6, lines 3-10; Figure 4; col. 14, lines 31-35)

At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain the patient information. One would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice. (Kraftson: col. 1, lines 58-64)

Regarding Applicant's assertion that the Kraftson surveys must be anonymous, it is noted Kraftson does not envision that the surveys be used only to gather patient satisfaction data or that there be complete patient anonymity with the surveys of the invention. (Kraftson col. 11, lines 24-58). The reference discusses patients filling out demographic and diagnostic/treatment sections of the questionnaire as requested by personnel.

(K) Applicant argues that Kimak and Kraftson do not teach or suggest receiving from the patient, prior to a visit with a physician, a ....form filled out by the patient..."

As per the recitation of "receiving from the patient, prior to a visit with a physician, a ....form filled out by the patient...", it is noted that the current language of the claim ("prior to a visit with a physician") does not require that the patient is a first time patient.

Kimak discloses presenting the patient's electronic medical record to the physician, before the patient visits the doctor to apprise the physician of the

patient's health status in the patient's absence. (par. 47,76, and 86). However, Kimak does not expressly disclose that the data is obtained from a questionnaire or that the questionnaire is mailed to a patient prior to an appointment. Kraftson discloses a method, further comprising the step of mailing the form to the patient prior to the appointment; and (col. 11, lines 9-13—Patients see doctors for the first time or on an ongoing basis to update information and may opt to fill out survey prior to any of their appts.)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RP

Robert Morgan
ROBERT W. MORGAN
PRIMARY EXAMINER
TECHNOLOGY CENTER 3600